Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

9/885d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

October 19, 2001

Our Reference: 2953087

Charles M. Umamoto, President
Hilo Fish Company, Inc.
55 Holomua Street
Hilo, Hawaii 96720

WARNING LETTER

Dear Mr. Umamoto:

We inspected your seafood processing facility, located at the above address, on July 10 and 11, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your histamine-forming fish and fishery products such as Tuna, Mahi-mahi, Marlin, etc. to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed some of the deviations on a Form FDA 483 (Inspectional Observations) and discussed them with Kyle M. Toma, Plant Manager, at the conclusion of the inspection. We are providing a copy of the FDA 483 for your reference. Your serious HACCP deviations include:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine forming species lists:

   (a) Critical limits at the Receiving Critical Control Point (CCP) that are not adequate to control histamine formation in scombrotoxin-forming fish

received directly from the fishermen. Because you receive large fish within 24 hours of death, you may have difficulty meeting your critical limit at receiving of internal temperatures no higher than 40°F. You should modify your critical limit for internal temperatures at receipt to be more meaningful in connection with the types of fish received, the mechanisms of handling and chilling used by the fishermen, and the time lapse from the estimated time of death to the time of receipt. Further, your critical limit for receiving fish above 45°F is more of a corrective action type of action rather than a critical limit. Please see FDA's Fish & Fishery Products Hazards & Controls Guidance, third edition, for recommended critical limits related to temperature controls on fishing vessels and at receipt by processors.

Further, to ensure that histamine-forming species were handled safely during harvest and while on-board the fishing vessel, FDA recommends that you supplement your internal temperature critical limit with sensory examination of the fish and receipt of harvest vessel records that show proper on-board handling with every lot received. At a minimum, the harvest vessel records must include the following information: method of capture, date and time of landing, estimated time of death, air/water temperatures, method of cooling, date/time cooling began, cooling rate, storage temperature, date and time of off-loading. The harvest vessel records you provided to FDA do not have all this information. Alternatively, histamine testing of the fish at receipt can be conducted instead of obtaining harvest vessel records.

Also, you should have an additional critical limit for scombrotoxin-forming fish that are not received directly from the fishing vessels, i.e., imported fresh fish. FDA recommends obtaining transport records to ensure that each lot received was maintained at 40°F or below throughout transit or check each lot at receipt to ensure that adequate ice or cooling media still surround the product.

(b) Critical limits at the Brining CCP that are not adequate to control histamine formation. Monitoring harvest vessel records and sensory examination are more appropriate controls at the Receiving CCP. At the Brining CCP, FDA recommends setting critical limits designed to chill and maintain the fish at 40°F or below. This can be accomplished by setting critical limits related to the adequacy of ice in the brine or the brine temperature with monitoring frequency of at least twice per day.

(c) Critical limits at the Evisceration and Butchering/Processing Fish CCPs that are not adequate to control histamine formation. Exposure of the fish to non-

refrigerated (>40°F) processing steps is a time and temperature concern. FDA recommends that the cumulative exposure during handling is limited to 8 hours above 40°F or to 4 hours above 40°F if any of that exposure time is at 70°F or higher. The operations can be lumped together for monitoring purposes since it is a cumulative exposure concern. If the total of these operations is very rapid, and never approaches the 4 hour exposure limitation, there may not be a significant hazard associated with these operations that necessitates a HACCP CCP and corresponding monitoring. If the CCPs are necessary, due to the total amount of exposure, monitoring should be done in such a way as to measure and control both the **time** and **temperature** of the exposure.

(d) Critical limits at the Storage CCP that are not adequate to control histamine formation. Your critical limit at this CCP calls for control of stored product at temperatures below 40°F. It also states that processing records are checked for product above 40°F and product is inspected in an unspecified manner. This latter action is more of a corrective action type of procedure than a critical limit. In fact, the action is in direct conflict with your written corrective action at this CCP that states that product that exceeds 40°F will be tested for histamine content.

Generally, FDA recommends maintenance of refrigerated storage coolers at 40°F or below, with continuous monitoring, in order to control histamine formation. Alternatively, if the stored fish and fish products are maintained on ice or chemical cooling media, FDA recommends that the adequacy of the ice or cooling media surrounding the fish is controlled with visual checks at least twice per day.

2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not consistently record internal temperatures of incoming fish at the Receiving CCP to control the hazard of histamine as listed in your plan for scombrotoxin-forming fish species. This is evidenced by your receiving records from June 16 through July 11, 2001.

You must immediately take appropriate steps to correct these violations. We may initiate regulatory action without further notice if you do not correct them. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen working days from receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of completed monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. Numerous deficiencies were noted in your HACCP plan regarding monitoring procedures, corrective actions, record keeping, and verification procedures. Your firm should perform a complete reassessment of your HACCP plan and correct these deficiencies. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Charles D. Moss, Acting

for Dennis K. Linsley
District Director
San Francisco District

Enclosure: Form FDA 483
cc: Kyle M. Toma, Plant Manager